510(k) Summary

JUL 2 1 2011

K111552

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

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Date Prepared: June 2, 2011

Device Name

Proprietary name: Elecsys T3 CalCheck 5
Common name: T3 CalCheck 5
Classification name: Single (specified) analyte controls (assayed and unassayed)

Predicate device

The Elecsys T3 CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed T3 CalCheck (K963167).

Device Description

The Elecsys T3 CalCheck 5 is a lyophilized product consisting of T3 in human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Intended use

The Elecsys T3 CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys T3 quantitative assay reagent on the indicated Elecsys and **cobas e** immunoassay analyzers, for in vitro diagnostic use only.

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Comparison Table

The table below compares Elecsys T3 CalCheck 5 with the predicate device, Elecsys T3 CalCheck (K963167). The predicate shows that T3 CalCheck 5 is substantially equivalent to T3 CalCheck, with several key similarities, especially the analyte. The shaded fields indicate similar characteristics between the candidate device and the predicate device.

Characteristic	Elecsys T3 CalCheck 5 (Candidate Device)	Elecsys T3 CalCheck (K963167)
Intended Use	The Elecsys T3 Calcheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys T3 quantitative assay reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.	For use in the verification of the calibration established by the Elecsys T3 regent on indicated Elecsys and **cobas e** immunoassay analyzers.
Analyte	T3	T3
Levels	Five	Three
Assay Measuring Range	0.300 – 10.0 nmol/L	0.300 – 10.0 nmol/L
Check Target Values	Check 1: ≤ 0.2 nmol/L Check 2: 2.0 nmol/L Check 3: 5 nmol/L Check 4: 8 nmol/L Check 5: 10 nmol/L	Check 1: 0 ng/ml Check 2: 1.6 ng/ml Check 3: 5.8 ng/ml
Format	Lyophilized	Lyophilized
Handling	Reconstitute Check 1, Check 2, Check 3, Check 4, and Check 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.	Reconstitute Check 1, Check 2, and Check 3 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted: • 20-25°C: 4 hours	Unopened: • Store at 2-8°C until expiration date Reconstituted: • 15-25°C: 4 hours
Matrix	Human serum matrix	Human serum matrix

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510(k) Summary, Continued

Performance Characteristics	The Elecsys T3 CalCheck 5 was evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

JUL 21 2011

Roche Diagnostics
c/o Ms. Kelly French
Manager, Regulatory Affairs
9115 Hague Road, PO Box 50416
Indianapolis, IN 46250-0416

Re: k111552
Trade Name: Elecsys T3 CalCheck 5
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed).
Regulatory Class: Class I, reserved
Product Codes: JJX
Dated: June 2, 2011
Received: June 3, 2011

Dear Ms. French:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K111552

Device Name: Elecsys T3 CalCheck 5

Indication For Use:

The Elecsys T3 CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys T3 reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

Prescription Use __X____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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